## II. AMENDMENT TO THE CLAIMS

Claim 1. (original) A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a human patient, providing a $C_{12}/C_{max}$ ratio of 0.55 to 0.85, said dosage form providing a therapeutic effect for at least about 12 hours.

Claim 2. (original) The dosage form of claim 1 wherein said hydrocodone is dispersed in a matrix comprising said controlled release material.

Claim 3. (original) The dosage form of claim 2 wherein said matrix is in multiparticulate form.

Claim 4. (cancelled)

Claim 5. (original) The dosage form of claim 3 wherein said multiparticulates are disposed in a pharmaceutically acceptable capsule.

Claim 6. (original) The dosage form of claim 1 which provides a $C_{12}/C_{max}$ ratio of 0.65 to 0.75.

Claim 7. (original) The dosage form of claim 1 which provides an in-vitro release of from 18% to about 42.5% by weight of the hydrocodone or salt thereof from the dosage form at one hour when measured by the USP Basket Method at 100 rpm in 700 ml of Simulated Gastric Fluid (SGF) for 55 minutes at 37°C and thereafter switching to 900 ml of Simulated Intestinal Fluid (SIF) at 37°C.

Claim 8. (original) The dosage form of claim 6 which provides an in-vitro release of from 18% to about 42.5% by weight of the hydrocodone or salt thereof from the dosage form at one hour when measured by the USP Basket Method at 100 rpm in 700 ml of Simulated Gastric Fluid (SGF) for 55 minutes at 37°C and thereafter switching to 900 ml of Simulated Intestinal Fluid (SIF) at 37°C.

Claim 9. (original) The dosage form of claim 1, which provides a dissolution rate in-vitro of the hydrocodone dosage form when measured by the USP Basket method at 100rpm in 900 ml aqueous buffer at a pH of 1.2 at 37°C from about 25 to about 65% by weight hydrocodone or salt thereof released after 2 hours, from about 45 to about 85% by weight hydrocodone or salt thereof released after 4 hours, and greater than about 60% by weight hydrocodone or salt thereof released after 8 hours.

Claim 10. (original) The dosage form of claim 1, which provides a dissolution rate in-vitro of the hydrocodone dosage form when measured by the USP Basket method at 100rpm in 900 ml aqueous buffer at a pH of 7.5 at 37°C from about 25 to about 65% by weight hydrocodone or salt thereof released after 2 hours, from about 45 to about 85% by weight hydrocodone or salt thereof released after 4 hours, and greater than about 60% by weight hydrocodone or salt thereof released after 8 hours.

Claim 11. (original) The dosage form of claim 1, which provides a $T_{max}$ of hydrocodone in said patient at from about 2 to about 8 hours after oral administration of the dosage form.

Claim 12. (original) The dosage form of claim 1, which provides a $T_{max}$ of hydrocodone in said patient at from about 3 to about 7 hours after oral administration of the dosage form.

Claim 13. (original) The dosage form of claim 1, which provides a $T_{max}$ of hydrocodone in said patient at from about 4 to about 6 hours after oral administration of the dosage form.

Claim 14. (currently amended) The dosage form of claim 1, which provides a plasma concentration of hydrocodone of at least 8 ng/ml at from about 2 to about 8 hours after administration and provides a plasma ~~plasma~~ concentration of hydrocodone of at least 6 ng/ml at about 12 hours after administration, based on oral administration of a dosage form containing 15 mg hydrocodone bitartrate.

Claim 15. (currently amended) The dosage form of claim 14, which provides a plasma ~~plasma~~ concentration of hydrocodone of at least 8 ng/ml at from about 3 to about 7 hours after administration.

Claim 16. (currently amended) The dosage form of claim 1 which provides a $C_{max}$ of hydrocodone which is less than 50% of the $C_{max}$ of an equivalent dose of an immediate release hydrocodone reference formulation (Lortab®).

Claim 17. (currently amended) The dosage form of claim 1 which provides a $C_{max}$ of hydrocodone which is less than 40% of the $C_{max}$ of an equivalent dose of an immediate release hydrocodone reference formulation (Lortab®).

Claim 18. (currently amended) The dosage form of claim 1 wherein the dosage form provides a time to 80% mean $C_{max}$ which is about 90% to about 110% of the time to 80% mean $C_{max}$ of an equivalent dose of an immediate release hydrocodone reference formulation (Lortab®).

Claim 19. (original) The dosage form of claim 1 which provides a time to 80% mean Cmax of hydrocodone from about .5 to about 1.5 hours.

Claim 20. (currently amended) The dosage form of claim 1 wherein the dosage form provides a time to 90% mean $C_{max}$ which is about 150% to about 250% of the time to 90% Cmax of an equivalent dose of an immediate release hydrocodone reference formulation (Lortab®).

Claim 21. (original) The dosage form of claim 1 which provides a time to 90% mean $C_{max}$ of hydrocodone from of about 1.5 to about 2.5 hours.

Claim 22. (original) The dosage form of claim 1 which provides a time to 90% mean $C_{max}$ of hydrocodone from about 1.8 to about 2.2 hours.

Claim 23. (original) The dosage form of claim 1 which maintains a plasma concentration within 80% of $C_{max}$ for about 1 to about 9 hours during the 12 hour dosing interval.

Claim 24. (original) The dosage form of claim 1 which maintains a plasma concentration within 80% of $C_{max}$ for about 4 to about 8 hours during the 12 hour dosing interval.

Claim 25. (original) The dosage form of claim 1 which maintains a plasma concentration within 90% of $C_{max}$ for about 1 to about 6.5 hours during the 12 hour dosing interval.

Claim 26. (original) The dosage form of claim 1 which maintains a plasma concentration within 90% of $C_{max}$ for about 2 to about 5 hours during the 12 hour dosing interval.

Claim 27. (currently amended) The dosage form of claim 1 which provides a $T_{max}$ at a time point 3 to 4 times later than the $T_{max}$ provided by an equivalent dose of an immediate release hydrocodone reference formulation (Lortab®).

Claim 28. (currently amended) The dosage form of claim 1, which provides a mean in-vivo absorption rate from administration to $T_{max}$ from about 1.5 mg/hour to about 5 mg/hour and provides a mean rate of absorption from $T_{max}$ to the end of the dosing interval which is less than about 0.5 mg/hour based on oral administration of a dosage form containing 15 mg hydrocodone bitartrate.

Claim 29. (original) The dosage form of claim 28 which provides a mean in-vivo absorption rate from administration to $T_{max}$ from about 2 mg/hour to about 4 mg/hour.

Claim 30. (original) The dosage form of claim 28 which provides a mean in-vivo absorption rate $T_{max}$ to the end of the 12 hour dosing interval which is from about 0.08 mg/hour to about 0.4 mg/hour.

Claim 31. (original) A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a human patient, providing a rate of absorption during the time period from $T_{max}$ to about 12 hours after oral administration of the dosage form which is from about 55% to about 85% of the rate of elimination during the same time period, said dosage form providing a therapeutic effect for at least about 12 hours.

Claim 32. (original) A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof together with controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a patient population, providing a $T_{max}$ of hydrocodone in-vivo at from about 2 to about 8 hours, and providing a $C_{12}/C_{max}$ ratio of 0.55 to 0.85, said dosage form providing a therapeutic effect for at least about 12 hours.

Claim 33. (currently amended) A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof ~~together~~ and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration providing a mean $C_{max}$ of hydrocodone which is less than about 50% of the mean $C_{max}$ of an equivalent dose of an immediate release hydrocodone reference formulation (Lortab®), said dosage form providing a therapeutic effect for at least 12 hours.

Claim 34. (currently amended) A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration providing a time to 80% mean $C_{max}$ which is about 90% to about 110% of the time to 80% mean $C_{max}$ of an equivalent dose of an immediate release hydrocodone reference formulation (Lortab®), said dosage form providing a therapeutic effect for at least 12 hours.

Claim 35. (original) A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration provides a mean in-vivo absorption rate from the time of oral administration to a human patient to $T_{max}$ of about 2 mg/hour to about 4 mg/hour and which provides a mean in-vivo absorption rate from $T_{max}$ to about 12 hours after administration which is from about 0.08 mg/hour to about 0.4 mg/hour, said dosage form providing a therapeutic effect for at least 12 hours, based on oral administration of a dosage form containing 15 mg hydrocodone bitartrate.

Claim 36. (original) A method of providing effective analgesia in a human patient for at least about 12 hours comprising orally administering a dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form providing after a first administration to a human patient a $C_{12}/C_{max}$ ratio of 0.55 to 0.85 and a therapeutic effect for at least about 12 hours.

Claim 37. (original) A process for the preparation of a solid oral controlled-release oral dosage, comprising incorporating an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, into controlled release material to make a dosage form suitable for twice-a-day administration to a human patient, wherein said dosage form after a first administration to a human patient provides a $C_{12}/C_{max}$ ratio of 0.55 to 0.85 and a therapeutic effect for at least about 12

hours.

Claim 38. (currently amended) A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a patient population, providing a mean $C_{12}/C_{max}$ ratio of 0.55 to 0.85, said dosage form providing a therapeutic effect for at least about 12 hours.

Claims 39-41 (cancelled)